K100538

JUN 22 2010

510(k) Summary

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

Submitter name, address, contact

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Date Prepared: February 22nd, 2010

Device Name

Proprietary names: Tina-Quant Ferritin Gen. 4 Assay

Common names: Ferritin Gen. 4 assay

Regulation: 21 CFR 866.5340

Classification names: Ferritin Immunological Test System

Product codes: DBF

Device Description

The Tina-quant Ferritin Gen. 4 assay employs an immunoturbidimetric test in which human ferritin agglutinates with latex particles coated with anti-ferritin antibodies. The precipitate is determined turbidimetrically at 570/800 nm.

Intended use

In vitro test for the quantitative determination of ferritin in human serum and plasma on Roche automated clinical chemistry analyzers.

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Indications for Use

Immunological in vitro immunoturbidometric test for the quantitative determination of ferritin in human serum and plasma using Roche/Hitachi clinical chemistry analyzers. Measurements obtained by this device are used in the aid of diagnosis of diseases affecting iron metabolism in conjunction with other clinical and laboratory findings.

Substantial equivalence

The Tina-quant Ferritin Gen. 4 assay is substantially equivalent to the Tina-Quant Ferritin assay cleared in K964282.

Substantial equivalence - comparison

Feature	Tina-quant Ferritin Gen. 4 Assay	Predicate Device: Tina-Quant Ferritin (K964283)
Intended Use	In vitro test for the quantitative determination of ferritin in human serum and plasma on Roche automated clinical chemistry analyzers.	Immunoturbidimetric assay for the in vitro quantitative determination of ferritin in human serum and plasma using automated clinical chemistry analyzers.
Assay Protocol	Same	Immunoturbidimetric Anti-ferritin antibodies bound to latex react with the antigen in the sample to form an antigen-antibody complex. Following agglutination, this is measured turbidimetrically.
Sample Type	Serum and Li-heparin, K_2-EDTA or K_3-EDTA plasma	Serum and heparinized, citrated or K_2 or K_3-EDTA plasma

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Feature	Tina-quant Ferritin Gen. 4 Assay	Predicate Device: Tina-Quant Ferritin (K964283)
Reagent Composition	R1: TRIS Buffer, pH 7.5, stabilizing polyclonal antibodies, NaCl preservative R3: Aqueous matrix containing latex particles coated with anti-human ferritin antibodies (rabbit); preservative, stabilizers	R1: TRIS Buffer, pH 8.2, stabilizing polyclonal antibodies, NaCl Preservative R2: Aqueous matrix containing latex particles coated with anti-human ferritin antibodies (rabbit); preservative, stabilizers
Labeled Instrument Platform	Roche/Hitachi	Roche/Hitachi
Calibrator	Same	C.f.a.s. Proteins
Calibration Frequency	Same	After lot change and as required following quality control procedures
Controls	Same	Precinorm and Precipath Protein
Reagent Stability	Unopened: Up to stated expiration date of 24 months Opened: 84 days, refrigerated on the analyzer	Unopened: Up to stated expiration date of 15 months Opened: 28 days, refrigerated on the analyzer
Measuring Range	Roche/Hitachi 902: 5 – 800 ng/mL Roche/Hitachi 912/917/Modular P: 5 – 1000 ng/mL	Roche/Hitachi 902: 5 – 400 ng/mL Roche/Hitachi 912/917/Modular P: 15 – 800 ng/mL

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<table>
<tr><th>Feature</th><th>Tina-quant Ferritin Gen. 4 Assay</th><th>Predicate Device: Tina-Quant Ferritin (K964283)</th></tr>
<tr><td>Precision</td><td>Precision was determined using human samples and controls in accordance with the CLSI EP5 requirements.
<table><tr><th></th><th colspan="2">Repeatability - Within run</th><th colspan="2">Intermediate Precision - Between Day</th></tr><tr><th>Sample</th><th>Mean ng/mL</th><th>% CV</th><th>Mean ng/mL</th><th>% CV</th></tr><tr><td>PNP</td><td>128</td><td>0.9</td><td>128</td><td>1.5</td></tr><tr><td>PPP</td><td>332</td><td>1.2</td><td>332</td><td>2.0</td></tr><tr><td>HS1</td><td>8.48</td><td>7.2</td><td>8.48</td><td>9.9</td></tr><tr><td>HS2</td><td>25.5</td><td>4.7</td><td>25.5</td><td>5.2</td></tr><tr><td>HS3</td><td>235</td><td>0.9</td><td>235</td><td>1.8</td></tr><tr><td>HS4</td><td>619</td><td>1.2</td><td>619</td><td>2.1</td></tr><tr><td>HS5</td><td>820</td><td>1.1</td><td>820</td><td>2.1</td></tr></table></td><td>Imprecision: Reproducibility was determined using human samples and controls in an internal protocol: n=21. The following results were obtained.
<table><tr><th></th><th colspan="2">Within run</th><th colspan="2">Between Day</th></tr><tr><th>Sample</th><th>Mean ng/mL</th><th>% CV</th><th>Mean ng/mL</th><th>% CV</th></tr><tr><td>HS</td><td>32</td><td>6.0</td><td>32</td><td>5.6</td></tr><tr><td>PNP</td><td>77</td><td>2.5</td><td>76</td><td>2.7</td></tr><tr><td>PPP</td><td>333</td><td>1.2</td><td>329</td><td>1.3</td></tr></table></td></tr>
<tr><td>Analytical Sensitivity</td><td>Limit of Blank = 3 ng/mL
Limit of Detection = 5 ng/mL</td><td>Lower Detection Limit = 15 ng/mL</td></tr>
<tr><td>Functional Sensitivity</td><td>Limit of Quantitation = 7 ng/mL</td><td>NA</td></tr>
<tr><td>Analytical Specificity</td><td>Same</td><td>The polyclonal antibodies used in the assay are specific for ferritin from human liver and also recognize ferritin from human spleen. The antibodies show no cross reactivity to the human ferritin H subunit; which is the major component of human heart ferritin.</td></tr>
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Feature	Tina-quant Ferritin Gen. 4 Assay	Predicate Device: Tina-Quant Ferritin (K964283)
Interferences	Icterus: No Significant interference up to an I index of 60 (approximate conjugated and unconjugated bilirubin concentration: 60 mg/dL) Hemolysis: No significant interference up to an H index of 500 (approximate hemoglobin concentration: 500 mg/dL) Lipemia (Intralipid): No significant interference up to an Intralipid concentration of 1000 mg/dL on Roche/Hitachi 912, 917 and MODULAR P analyzers and up to an Intralipid concentration of 800 mg/dL on Roche/Hitachi 902 analyzers. There is poor correlation between the Intralipid concentration (corresponds to turbidity) and triglycerides concentration. Rheumatoid factors <1200 IU/ml do not interfere. No high-dose hook effect is seen up to a ferritin concentration of 80000 ng/mL on Roche/Hitachi 902/912/917/MODULAR P analyzers. Drugs: No interference was found at therapeutic concentrations using common drug panels.	Icterus: No Significant interference up to an I index of 60 (approximate conjugated and unconjugated bilirubin concentration: 60 mg/dL) Hemolysis: No significant interference up to an H index of 500 (approximate hemoglobin concentration: 500 mg/dL) Lipemia (Intralipid): No significant interference up to an L index of 750 (approximate triglyceride concentration: 1500 mg/dL). There is poor correlation between turbidity and triglyceride concentration. Rheumatoid factors <100 IU/ml do not interfere. A high-dose hook effect may occur at ferritin concentrations above 20,000 ng/mL (Roche/Hitachi 911/912/917/MODULAR P).

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Feature	Tina-quant Ferritin Gen. 4 Assay	Predicate Device: Tina-Quant Ferritin (K964283)
Expected Values	Men (20-60 yrs): 30 – 400 ng/mL Women (17 – 60 yrs): 15 – 150 ng/mL	Men: 30 – 400 ng/mL Women: 15 -150 ng/mL Children (3 months – 16 years): 20 – 200 ng/mL 2^{nd} – 3^{rd} month: 80 – 500 ng/mL 1^{st} month: 150 – 450 ng/mL Umbilical cord blood: 50 - 250 ng/mL
Method Comparison	A comparison of the Roche Tina-quant Ferritin Gen. 4 assay on the Roche/Hitachi 917 analyzer (y) with the Roche Tina-quant Ferritin assay on the same analyzer (x) using human serum and plasma samples gave the following correlation (ng/mL): Passing Bablok: y = 0.987x + 0.040 tau = 0.983 Linear regression: y = 0.987x + 0.591 r = 0.999 Number of samples measured: 94 The sample concentrations were between 15.0 and 775 ng/mL (according the measuring range of the predicate device).	

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food & Drug Administration
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Silver Spring, MD 20993

Roche Diagnostics
c/o Ms. Kathie Goodwin, MBA, MT (ASCP)BB, RAC
Regulatory Affairs Principal
9115 Hague Road, PO Box 50416
Indianapolis, IN 46250-0416

JUN 2 2 2010

Re: k100538
Trade/Device Name: Tina-Quant Ferritin Gen. 4
Regulation Number: 21 CFR § 866.5340
Regulation Name: Ferritin Immunological Test System
Regulatory Class: Class II
Product Code: DBF
Dated: May 7, 2010
Received: May10, 2010

Dear Ms. Goodwin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Maria M Chan

Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): k100538

Device Name: Tina-Quant Ferritin Gen. 4

Indications for Use:

Immunological *in vitro* immunoturbidometric test for the quantitative determination of ferritin in human serum and plasma using Roche/Hitachi clinical chemistry analyzers. Measurements obtained by this device are used in the aid of diagnosis of diseases affecting iron metabolism in conjunction with other clinical and laboratory findings.

Prescription Use ___x___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Reena Philip

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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